

WE CLAIM:

1. A method of male contraception comprising the step of:  
administering to a non-sterile male subject a predetermined amount of an androgen  
which is sufficient to render said male subject reversibly sterile for a predetermined  
5 period of time and which provides said male subject with blood levels of LH and  
FSH of 2.5 IU/L or less and testosterone of 10 nmol/liter or less.

2. A method of male contraception comprising the step of:  
administering to a non-sterile male subject a predetermined amount of a non-5 $\alpha$ -  
reducible androgen which is sufficient to render said male subject reversibly sterile  
for a predetermined period of time.

3. The method of claims 1 or 2 wherein said androgen is MENT  
or MENT Ac.

4. The method of claim 3 wherein said predetermined period of  
time is at least 1 day and said predetermined amount of MENT or MENT Ac is an  
amount which is sufficient to render said male subject reversibly sterile each day  
over said predetermined period.

5. The method of claim 4 wherein said predetermined period of  
time is a plurality of days and said predetermined amount of MENT or MENT Ac is  
an amount which is sufficient to render said male subject reversibly sterile each day  
over said predetermined period.

6. The method of claim 5 wherein said predetermined period of  
time is at least 7 days and said predetermined amount of MENT or MENT Ac is an  
amount which is sufficient to render said male subject reversibly sterile each day  
over said predetermined period.

7. The method of claim 5 wherein said predetermined period of  
time is at least 30 days and said predetermined amount of MENT or MENT Ac is  
an amount which is sufficient to render said male subject reversibly sterile each day  
over said predetermined period.

8. The method of claim 5 wherein said predetermined period of  
time is at least 180 days and said predetermined amount of MENT or MENT Ac is  
an amount which is sufficient to render said male subject reversibly sterile each day  
over said predetermined period.

9. The method of claim 3 wherein said predetermined bioavailable amount of MENT or MENT Ac ranges from between about 200 to about 2000 micrograms/day.

5 10. The method of claim 9 wherein said predetermined bioavailable amount of MENT or MENT Ac ranges from between about 400 to about 1500 micrograms/day.

11. The method of claim 10 wherein said predetermined bioavailable amount of MENT or MENT Ac ranges from between about 500 to about 1000 micrograms/day.

10 12. The method of claim 11 wherein said predetermined bioavailable amount of MENT or MENT Ac provides mean steady state serum levels of 1.0 nmol/Liter/day or greater.

13. The method of claim 1 wherein said predetermined amount of androgen is sufficient to provides said male subject with blood levels of LH and  
15 FSH of 2.0 IU/L or less and testosterone of 5 nmol/liter or less.

14. The method of claim 13 wherein said predetermined amount of androgen is sufficient to provides said male subject with blood levels of LH and FSH of 1.5 IU/L or less and testosterone of 4 nmol/liter or less.

15. The method of claim 14 wherein said predetermined amount  
20 of androgen is sufficient to provides said male subject with blood levels of LH and FSH of 1.0 IU/L or less and testosterone of 3 nmol/liter or less.

16. The method of claim 3 wherein said MENT or MENT Ac is substantially the only sterilizing agent administered to said male subject for the purposes of contraception.

25 17. The method of claims 1 or 2 wherein said predetermined amount of androgen is administered to said subject by injection.

18. The method of claims 1 or 2 wherein said predetermined amount of androgen is administered to said subject by implant.

30 19. The method of claims 1 or 2 wherein said predetermined amount of androgen is administered to said subject by topical application.

20. The method of claim 14 wherein said predetermined amount of androgen is administered to said subject as a cream, lotion, gel or in a transdermal patch.

5 21. The method of claims 1 or 2 wherein said predetermined amount of androgen is administered to said subject orally.

10 22. A male contraceptive comprising: at least a predetermined amount of an androgen which is sufficient to render said male subject reversibly sterile for a predetermined period of time and which provides said male subject with blood levels of LH and FSH of 2.5 IU/L or less and testosterone of 10 nmol/liter or less and a pharmaceutically acceptable carrier.

23. The male contraceptive of claim 22 wherein said predetermined amount of an androgen is sufficient provides said male subject with blood levels of LH and FSH of 2.0 IU/L or less and testosterone of 5 nmol/liter or less.

15 24. The male contraceptive of claim 23 wherein said predetermined amount of an androgen is sufficient provides said male subject with blood levels of LH and FSH of 1.5 IU/L or less and testosterone of 4 nmol/liter or less.

20 25. The male contraceptive of claim 24 wherein said predetermined amount of an androgen is sufficient provides said male subject with blood levels of LH and FSH of 1.0 IU/L or less and testosterone of 3 nmol/liter or less.

26. The male contraceptive of claim 23 wherein said predetermined period is at least 30 days.

25 27. The male contraceptive of claim 26 wherein said predetermined period is at least 180 days.

28. The male contraceptive of claim 25 wherein said predetermined period is at least 30 days.

30 29. The male contraceptive of claim 28 wherein said predetermined period is at least 180 days.

30. The male contraceptive as in one of claims 22 through 25 wherein pharmaceutically acceptable carrier is suitable for injection or intravenous administration.

31. The male contraceptive as in one of claims 22 through 25 wherein said pharmaceutically acceptable carrier is suitable for topical application.

32. The male contraceptive as in one of claims 22 through 25 wherein said pharmaceutically acceptable carrier is a cream, lotion, gel or a transdermal patch.

33. The male contraceptive as in one of claims 22 through 25 wherein said pharmaceutically acceptable carrier is suitable for administration orally.

34. The male contraceptive as in one of claims 22 through 25 wherein said pharmaceutically acceptable carrier is an implant or pump.

35. A male contraceptive comprising: a predetermined amount of a non-5 $\alpha$ -reducible androgen which is sufficient to render said male subject reversibly sterile for at least one day and a pharmaceutically acceptable carrier.

36. The male contraceptive of claim 35 wherein said non-5 $\alpha$ -reducible androgen is MENT, MENT Ac or salts thereof provided in a bioavailable amount of between about 500 and about 1000 micrograms per day.

37. The male contraceptive of claim 36 wherein said pharmaceutically acceptable carrier is selected from the group consisting of an implant, a topical gel and a transdermal patch.

38. A method of androgen replacement therapy comprising the step of: administering to a male subject an amount of an androgen which is sufficient to provide therapeutic efficacy without causing sterility.

39. The method of claim 38 wherein said androgen is provided in an amount which is sufficient to maintain blood levels of LH and FSH above 2.5 IU/L and testosterone above 10 nmol/liter.

40. The method of claim 39 wherein said androgen is not 5 $\alpha$ -reducible.

41. The method of claim 40 wherein said androgen is MENT, MENT Ac, or salts thereof provided in a bioavailable amount of between greater than zero and less than about 500 micrograms per day.

42. A dosage form for androgen replacement therapy comprising an amount of an androgen which is sufficient to provide therapeutic efficacy without causing sterility and a pharmaceutically acceptable carrier.

5 43. The dosage form of claim 42 wherein said androgen is provided in an amount which is sufficient to maintain blood levels of LH and FSH above 2.5 IU/L and testosterone above 10 nmol/liter.

44. The dosage form of claim 43 wherein said androgen is not 5 $\alpha$ -reducible.

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